5.0 510(k) Summary

JUN 18 2014

General Provisions	Submitter Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 208-4789 (801) 253-6919 Susan Christensen May 22, 2014 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name:	Merit Centros® and CentrosFLO® Long-Term Hemodialysis Catheter Implanted Hemodialysis Catheter Catheter, Hemodialysis, Implanted
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	Merit Centros® Long-Term Hemodialysis Catheter Catheter, Hemodialysis, Implanted K092597 Merit Medical Systems, Inc.
Classification	Class 21 CFR § FDA Product Code: Review Panel:	III 876.5540 MSD Gastroenterology/Urology
Intended Use	The Merit Centros and CentrosFLO Long-Term Hemodialysis Catheter are indicated for use in attaining long-term vascular access for hemodialysis and apheresis. It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient. This catheter is indicated for > 30 days, (long-term) placement.	
Device Description	The Centros and CentrosFLO Long-Term Hemodialysis Catheters are dual lumen, 15FR catheters available in a straight configuration with multiple lengths. The catheter comes with a stiffening stylet that can be used for over-the-wire placement. The stiffening stylet has a female Luer which is over-molded on a nylon shaft with a tapered distal tip. Distal to the female Luer is a rotating male locking collar which can be used to attach the stylet to the catheter. The catheter lumens are D-shaped and made from radiopaque Carbothane. The distal end design is a fixed length pre-formed split-tip, with (CentrosFLO) or without (Centros) side-holes. The distal venous lumen extends past the arterial lumen, and includes a guide wire slit for insertion by the optional over-the-wire placement technique. The proximal device contains a fixed polyester cuff, an integrated bifurcation, suture wing, and extension legs with color coded occlusion clamps and Luer connectors (red and blue for the arterial and venous lumens respectively). The lumen priming volumes are printed on ID tags within the occlusion clamps. The trade name and cuff-to-tip length are printed on the catheter bifurcation. The procedure kits include the necessary accessories to correctly insert the catheter.	

Comparison to Predicate Device	The technological characteristics including design, intended use, materials, kit components, packaging, and labeling of the subject Centros and CentrosFLO Long-Term Hemodialysis Catheter are substantially equivalent to those of the predicate device. Both the Centros and CentrosFLO catheters now come with a stiffening stylet for use in placing the catheter using the over-the-wire placement method.
Safety & Performance Tests	FDA guidance and recognized performance standards have been established for Implanted Blood Access Devices for Hemodialysis under Section 514 of the Food, Drug and Cosmetic Act. A battery of tests was performed based on the requirements of the below recognized performance standards and draft guidance, as well as biocompatibility, sterilization, and labeling standards and guidance. Conformity to these standards demonstrates that the proposed Merit Centros/CentrosFLO Long-Term Hemodialysis Catheters met the standards' established acceptance criteria applicable to the safety and efficacy of the device. Performance testing was conducted based on the risk analysis and based on the requirements of the following international standards/documents: • FDA Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, 1995 • FDA Draft Guidance for Industry and Food and Drug Administration Staff – Class II Special Controls Guidance Document Implanted Blood Access devices for Hemodialysis June 28, 2013 • ISO 10555-1:2013, Sterile, Single-Use Intravascular Catheters, Part 1: General Requirements. • ISO 10555-3:2013, Sterile, Single-Use Intravascular Catheters, Part 3: Central Venous Catheters. • ISO 594-1:1986, Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 1: General Requirements. • ISO 594-2:1998, Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 2: Lock fittings • ISO 11070: Sterile Single Use Intravascular Catheter Introducers • ISO 11135-1:2007, *Sterilization of health care products – routine control of a sterilization process for medical device* • ISO 10993-1:2009, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process*, and FDA guidance *Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices*, May 1, 1995

Safety & Performance Tests cont.	Performance Testing-Bench • Dimensional Verification • Stylet removal from catheter • Guidewire slit liquid leakage • Stylet insertion in catheter • Visual inspection • Guidewire passage through stylet • Stylet Protrusion • Force at break stylet hub to shaft • Stylet Luer gauging • Stylet Luer separation force • Stylet Luer unscrewing torque • Stylet Luer ease of assembly • Stylet Luer resistance to overriding • Stylet Luer stress cracking The results of the testing demonstrated that the subject Merit Centros/CentrosFLO Long-Term Hemodialysis Catheter met the predetermined acceptance criteria applicable to the safety and efficacy of the device.
Summary of Substantial Equivalence	Based on the indications for use, design, safety and performance testing, the subject Merit Centros/CentrosFLO Long-Term Hemodialysis Catheter meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Centros Long-Term Hemodialysis Catheter, K092597 manufactured by Merit Medical Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 18, 2014

Merit Medical Systems, Inc.
Susan Christensen
Principal Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, UT 84095

Re: K141363
Trade/Device Name: Merit Centros® and CentrosFLO® Long-Term Hemodialysis Catheter
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: May 22, 2014
Received: May 23, 2014

Dear Susan Christensen,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141363

Device Name
Merit Centros® and CentrosFLO® Long-Term Hemodialysis Catheter

Indications for Use *(Describe)*

The Merit Centros and CentrosFLO Long-Term Hemodialysis Catheter are indicated for use in attaining long-term vascular access for hemodialysis and apheresis. It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient. This catheter is indicated for > 30 days, (long-term) placement.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Herbert P. Lerner -S
2014.06.18 12:13:31 -04'00'

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